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| 10/087,014 | 03/01/2002 | Henrik Hansen | 12013/59301 | 2646 |
| 23838 7590 02/26/2007 KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005 | | | EXAMINER TSOY, ELENA | |
| | | | ART UNIT 1762 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/087,014

Applicant(s)

HANSEN ET AL.

Examiner

Elena Tsoy

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 19, 25-29, 31, 33, 35, 37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) 29 and 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 19, 25-28, 31, 33, 35, 37 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Response to Amendment

1. Amendment filed on January 8, 2007 has been entered. Claims 1-16, 18-19, 25-29, 31, 33, 35, 37, and 39-45 are pending in the application. Claims 29 and 40-45 are withdrawn from consideration as being directed to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed discloses that a drum may have a stellate cross-section to maximize coating efficiency and to prevent damage of the devices to be coated (See published application, P17) or may be equipped with an air suspension system for suspending the medical implant aloft in the pan coat drum 41 in accord with an *alternative* embodiment (See published application, P27). Thus, the specification as filed does not have support for **both** stellate cross-section **and** air suspension system for suspending the medical implant aloft.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification as filed does not describe how to use a drum having **both** stellate cross-section **and** air suspension system for suspending the medical implant aloft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12, 13, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al (US 20040261698) in view of Lucke (5,302,201).

Roorda et al disclose a method of coating stents (See P16) for the delivery of therapeutic (See P21) comprising: placing stents into a rotatable pan 204 including a drum, tumbling the stents by rotating the drum about a longitudinal axis of the drum (obviously stents are free to strike the bottom or the wall of the drum) (See Fig. 2; P17), spraying a therapeutic in a solvent carrier over the tumbling stents (See P18); and removing the solvent using hot air (claimed **heated** compressible fluid) of 15-200 °C (i.e. drying by drawing air) (See P19).

Roorda et al fail to teach that that the drum has a plurality of orifices in the wall (Claims 12 and 13).

Lucke teaches that coating cores in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22), spraying the coating materials through nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas, allows to achieve high quality of coated cores (See column 4, lines 34-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated cores of Roorda et al using a rotary drum of Lucke containing a plurality of orifices, where the applied coating is dried by blowing a gas with the expectation of providing the desired high quality of coated cores, as taught by Lucke.

5. Claims 1-3, 25-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Lucke, further in view of Forster (US 4,581,242).

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Roorda et al in view of Lucke are applied here for the same reasons as above. Roorda et al in view of Lucke fail to teach that implants are suspended above an internal surface of the drum (Claims 1, 25).

Forster teaches that blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) or **fluidized** coating systems allows drying the objects at all levels (See column 1, lines 17-30) by *expanding* the bed of particles (i.e. suspending the medical implants, i.e. holding them aloft) (See column 1, lines 42-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified a method of Roorda et al to blow air up through the articles in the coating pan to suspend the medical implants with the expectation of providing the desired drying the objects at all levels as they are held expanded (aloft), as taught by Forster.

As to claims 3 and 26, it is well known in the art that inert gas should be used in case a bioactive coating is sensitive to air.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas in Roorda et al in view of Forster with the expectation of providing the desired high quality bioactive coating if a bioactive coating is sensitive to air.

As to claims 28, blowing of air or gas does not continue indefinitely and thus is "periodic".

6. Rejection of claims 1-4, and 31 under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster, further in view of Lucke has been withdrawn due to amendment.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Lucke, further in view of Forster, and further in view of Ryder, Jr., et al (US 3,283,362).

Roorda et al in view of Lucke in view of Forster are applied here for the same reasons as above. Roorda et al in view of Lucke in view of Forster fail to teach that the drum has a stellate cross-section.

However, Ryder, Jr., et al teach that axially aligned radial vanes (claimed stellate cross-section) in drums provide mixing with minimum power input (See column 2, lines 1-8).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided drums of Roorda et al in view of Lucke in view of Forster with axially aligned radial vanes (claimed stellate cross-section) with the expectation of providing the desired mixing with minimum power input, as taught by Ryder, Jr., et al.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Lucke, further in view of Forster, and further in view of JP 10034643A.

Roorda et al in view of Lucke in view of Forster are applied here for the same reasons as above. Roorda et al in view of Lucke in view of Forster fail to teach that the drum has a stellate cross-section.

However, JP 10034643A teaches that a rotary drum may be provided with vanes attached to a rotary shaft to shorten mixing time (See Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided drums of Roorda et al in view of Lucke in view of Forster with axially aligned radial vanes (claimed stellate cross-section) with the expectation of providing the desired shortened mixing time, as taught by JP 10034643A.

9. Claims 5, 6, 8, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Lucke, further in view of Forster, and further in view of Schwartz et al (US 6,607,598).

Roorda et al in view of Lucke in view of Forster are applied here for the same reasons as above. Roorda et al in view of Lucke in view of Forster fail to teach that the medical implant has a masking material on at least one surface (Claim 5).

Schwartz et al state that *masking* techniques are known in the art for partial coating of stents to result in coating of predetermined stent segments (See column 11, line 67; column 12, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used known masking techniques for coating stents in Roorda et al in view of Lucke in view of Forster with the expectation of providing the desired coating of predetermined segments of the stents, as taught by Schwartz et al.

As to claim 6, limitations of claim 6 are obvious because collection of any fluid inherently requires a reservoir.

As to claim 8, Schwarz '598 teaches multiple layers (col. 7, line 40).

10. Claims 7, 9-11, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Lucke, further in view of Forster, and further in view of Dunajtschik (US 4,586,457).

Roorda et al in view of Lucke in view of Forster are applied here for the same reasons as above. Roorda et al in view of Lucke in view of Forster fail to teach that air is re-circulated (Claims 7, 9).

Dunajtschik teaches that it is possible in principle to completely seal the inner space of the coating drum 2 against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air (See column 7, lines 14-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have completely sealed the inner space of the coating drum in Roorda et al in view of Lucke in view of Forster against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air with the expectation of providing the desired isolation of operation, as taught by Dunajtschik.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Lucke, further in view of Forster, and further in view of Fernandez et al (US 3,696,188).

Roorda et al in view of Lucke in view of Forster are applied here for the same reasons as above. Roorda et al in view of Lucke in view of Forster fail to teach that cores coated with a first and a second bioactive coating layers.

Fernandez et al teach that inert cores can be coated with multiple bioactive coating layers depending on intended use of a final product (See column 3, lines 5-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated inert cores in Roorda et al in view of Lucke in view of Forster with multiple bioactive coating layers depending on intended use of a final product, as taught by Fernandez et al.

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As to recycling, while the references fail to specifically teach recycling the therapeutic agent, Examiner notes that pharmaceuticals are very expensive. In a spray coating operation, a large quantity of coating material is "lost" and misses its targets. It is Examiner's position that one of ordinary skill in the art would provide a recycling operation to recover the lost pharmaceuticals to be used in a later coating operation so as to maximize manufacturing profits.

Response to Arguments

11. Applicants' arguments filed January 8, 2007 have been fully considered but they are not persuasive.

(A) Applicants argue that although the Office action cites to Forster (4,581,242) when rejecting the use of compressible fluid to maintain the medical implant aloft, nowhere in Forster is there a discussion or suggestion to inject compressible fluids to maintain the implant aloft in the drum. The cited portion of Forster, (col. 1, lines 18-30; 42-50) is a background section that addresses how coated tablets may be dried with drying air or gas. Through this drying process, Forster notes that the objects being coated "will have a tendency to expand rather than densify the bed." Thus, the tablets in Forster are not suspended or held aloft as contended by the Office action. Rather, they remain on top of one another, merely in a less dense state. Moreover, even if Forster did disclose or suggest suspending the tablets, there is no teaching that would properly combine this step with the other references to teach all the steps of the claimed inventions.

The Examiner respectfully disagrees with this argument. Forster teaches that blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) or **fluidized** coating systems allows drying the objects at all levels (See column 1, lines 17-30) by *expanding* the bed of particles (i.e. suspending the medical implants, i.e. holding them aloft) (See column 1, lines 42-50). In other words, Forster teaches that blowing air or gas up through the bed of objects in a side vented coating pan allows drying the objects at all levels just like in **fluidized** coating systems. Therefore, *expanding* the bed of particles implies holding the particles aloft as in the **fluidized** coating systems.

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(B) Applicants argue that while citing several references when rejecting claim 12, the Office action does not identify any specific portion of any of the references relevant to drawing a fluid into a drum as in the claim.

The Examiner respectfully disagrees with this argument. Roorda et al teach removing the solvent using hot air (claimed heated compressible fluid) of 15-200 °C (i.e. drying by drawing air into a drum) (See P19); and Lucke teaches that coating cores in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22), spraying the coating materials through nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas (claimed drawing gas into a drum), allows to achieve high quality of coated cores (See column 4, lines 34-35).

(C) Applicants argue that none of Roorda, Lucke and Forster references disclose or suggest heating the compressible fluid and heating the rotatable drum as in the claim. Allegedly, in each case, the air is heated, however, nowhere is the additional affirmative step of heating the drum addressed. As taught in the applicant's disclosure (see ¶ 20), this additional step is not a mere design choice, rather than simply heating the air alone, as it may serve to better facilitate the drying of the coating.

The argument is unconvincing. In contrast to Applicants argument, heating the drum is NOT recited in the claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., heating the drum) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). However, if even claims do recite the step of heating the drum, drawing the heated air (taught by Roorda) would obviously heat the drum.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762

ELENA TSOY
PRIMARY EXAMINER

ETsoy

February 21, 2007